

REMARKS

Reconsideration of this application, as amended, is respectfully requested.

Claims 1-25 are pending. Claims 8-23 stand rejected. In this response, claims 8, 13, 17 and 22 have been amended. Claim 16 has been canceled. No claims have been added. Support for the amendments is found in the specification, the drawings, and in the claims as originally filed. Applicants submit that the amendments do not add new matter. Applicants reserve all rights with respect to the applicability of the Doctrine of Equivalents.

Objections

The Examiner has objected to the priority claim. The present application is a National Phase of International Application No. PCT/SG2005/000087, filed on March 18, 2005, which claims priority from Singapore Patent Application No. 200401544-2, filed on March 22, 2004. The priority claim to Singapore Patent Application No. 200401544-2 was submitted in a preliminary amendment to the specification on September 22, 2006. The claim for priority thus satisfies 37 CFR § 1.55(a) given that it was made on the filing date. MPEP § 201.14(b) states that the claim to priority need be in no special form. The filing receipt mailed June 2, 2007 acknowledges the priority claim to Singapore Patent Application No. 200401544-2, filed on March 22, 2004. Thus, the Patent and Trademark Office had proper notice of the priority claim. In view of this, applicants respectfully request the withdrawal of the objection to the priority claim.

The Examiner has objected to the declaration. A new declaration is being submitted herewith. In view of this, applicants respectfully request the withdrawal of the objection to the declaration.

The Examiner has objected to the figures 3-5. Replacement drawing sheets are being supplied herewith in compliance with 37 CFR 1.121(d). In view of this, applicants respectfully request the withdrawal of the objections to figures 3-5.

The Examiner objected to the specification and figure 1, pointing to the number 2. Appropriate correction to the specification has been made. In view of this, applicants respectfully request the withdrawal of the objections to the specification and figure 1.

Rejections- 35 U.S.C. § 103(a)

Claims 8-11, 13, 15 and 18-23 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over WO 02/06058 to Isotis N.V. ("Isotis") in view of U.S. Patent No. 6,149,688 to Brosnahan et al. ("Brosnahan"). Claims 8 and 16-17 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Isotis in view of Brosnahan and further in view of U.S. Patent No. 6,063,894 to Phipps et al. ("Phipps"). Claims 8 and 13-14 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Isotis in view of Brosnahan and further in view of U.S. Publication No. 2004/0258732 to Shikinami ("Shikinami"). Claims 8 and 12 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Isotis in view of Brosnahan and further in view of U.S. Patent No. 6,712,845 to Hossainy ("Hossainy").

Applicants respectfully submit that claim 8 is not obvious over the combination of references for several reasons. It is submitted that the reference do not teach or suggest every feature of amended independent claim 8, indeed Isotis teaches away from the proposed combination of references. In addition, given that Phipps is in a different technology class and addresses a different problem than Isotis and Brosnahan, it is submitted that the proposed combination of references can only be the result of impermissible hindsight reasoning based

upon applicants own disclosure, and that a person of ordinary skill in the art at the time of applicants' invention would not have combined Phipps with Isotis and Brosnahan. Nevertheless, even if combined the combination of references lacks the feature of ultrasonic leaching to provide controlled differential leaching of a first polymer at the surface and core.

Independent claim 8 has been amended to include features of previously presented dependent claim 16. As amended, independent claim 8 is directed to a method of fabrication of a scaffold comprising, *inter alia*, "leaching the scaffold in an ultrasonic bath of solvent to remove a first polymer of the at least two polymers, all other polymers of the at least two polymers being inert to the solvent, wherein leaching of the first polymer is controlled so that removal of the first polymer occurs to a greater extent at a surface of the scaffold, and to a lesser extent at a core of the scaffold." In application, the solvent may partially dissolve the first polymer while the ultrasonic vibrations remove the loose particles in the polymer blend. The depth of penetration of the effect may remove the first polymer to a greater extent at a surface of the scaffold than at a core of the scaffold. Thus, the effect of the ultrasonic leaching allows for the controlled differential leaching of the surface and core.

Isotis ('058) discloses mixing two polymers and removing one of the polymers by adding a solvent. In particular, Isotis is directed to providing a porous body with homogenously distributed and interconnected pores throughout the porous body. See page 2, lines 22-24. Isotis discloses that the solvent should "achieve a substantially complete removal of the soluble particles." See page 9, lines 21-23. Accordingly, Isotis discloses the importance of achieving a a structure with a homogenous distribution of interconnected pores, and does not disclose or

suggest ultrasonic leaching to provide controlled differential leaching of a first polymer at the surface and core.

Brosnahan ('688) discloses methods of forming an artificial bone graft implant in which a porous portion can be created by injection molding a HAp slurry containing a binder, and burning the binder out during sintering to create pores. Brosnahan additionally discloses a unitary structure having a gradient of pore sizes from the center to outer portion. Brosnahan is completely unconcerned with leaching of a first polymer, and does not disclose or suggest forming the unitary structure having a gradient of pore sizes utilizing a leaching technique. Accordingly, Brosnahan also does not disclose or suggest ultrasonic leaching to provide controlled differential leaching of a first polymer at the surface and core.

The Examiner states at page 6 of the Office Action that it would have been obvious to modify the process of Isotis in view of Brosnahan including "leaching the sacrificial polymer as taught by the '508 publication and provide a porosity gradient as taught in the '688 patent" because this would provide "an implant with a porosity which allows bone tissue ingrowth for repair." Applicants respectfully disagree because Isotis teaches away from this. As described at page 1, lines 18-21 of Isotis, sintering methods such as Brosnahan result in structures with unacceptable shape and morphology, and as described at page 2 line 6, control over the pore size and porosity remains difficult. Accordingly, Isotis strongly discourages forming a structure similar to the one achieved in Brosnahan, and instead stresses the importance of forming a structure with a homogenous distribution of interconnected pores.

Phipps ('894) discloses a process of ultrasonic purification of polymers in which any impurities remaining from the polymerization process are removed from the polymer.

“Generally, leaching is conducted until greater than about 99% of leachant is removed.” Col. 8, lines 3-4. Thus, Phipps discloses a process for complete removal of a leachant, and does not disclose or suggest ultrasonic leaching to provide controlled differential leaching of a first polymer at the surface and core. Moreover, as stated on page 11 of the present response, Phipps is in an different technology class than Isotis and Brosnahan, and it is submitted that the proposed combination of references can only be achieved by the result of hindsight and *ex post facto* analysis which is neither permitted nor allowable. A skilled searcher, as at the priority date of the present application, would therefore tend to not find Phipps and combine it with Isotis and Brosnahan. Phipps is not even addressing a similar problem.

The Examiner relies upon Shikinami ('732) as disclosing compression moulding. The Examiner relies upon Hossiany ('845) as disclosing specific solvents. Applicants respectfully submit that Shikinami and Hossiany do not remedy the deficiencies of Isotis, Brosnahan and Phipps as discussed above.

Claims 9-15 and 17-23 are dependent, either directly or indirectly, thereon and are patentable for at least the same reasons as independent claim 8. Accordingly, Applicants respectfully request the withdrawal of the rejections of claims 8-15 and 17-23 under 35 U.S.C. § 103(a).

Claim 22 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Isotis in view of Brosnahan. In addition to the reasons provided above with regard to independent claim 8, Applicants respectfully submit that the reference do not teach or suggest every feature of

dependent claim 22, indeed Isotis teaches away from the proposed combination of references. Further, given that Phipps is in a different technology class and addresses a different problem than Isotis and Brosnahan, it is submitted that the proposed combination of references can only be the result of impermissible hindsight reasoning based upon applicants own disclosure, and that a person of ordinary skill in the art at the time of applicants' invention would not have combined Phipps with Isotis and Brosnahan. Nevertheless, even if combined the combination of references lacks the feature of ultrasonic leaching to produce a graded porosity.

Amended independent claim 22 requires, *inter alia*, “wherein the leaching produces a graded porosity in the scaffold with a higher porosity at the surface of the scaffold, and a lower porosity at the core of the scaffold.”

As described above, Isotis is directed to providing a porous body with homogenously distributed and interconnected pores throughout the porous body. As described above, Brosnahan discloses burning of binder during a sintering operation to create a porous body. Brosnahan also discloses a unitary structure having a gradient of pores from the center to outer portion. Phipps is directed to a process for complete removal of a leachant.

None of the references, alone or in combination disclose or suggest utilizing leaching to produce a graded porosity in the scaffold. Indeed Isotis teaches away from achieving the structure of Brosnahan.

Accordingly, applicants respectfully request the withdrawal of the rejection of claim 22 under 35 U.S.C. § 103(a).

It is respectfully submitted that in view of the amendments and arguments set forth herein, the applicable rejections and objections have been overcome. If there are any additional charges, please charge Deposit Account No. 02-2666.

Respectfully submitted,

BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN LLP

Date: January 8, 2010

By: /Jacob Aikin/
Jacob T. Aikin
Reg. No. 62,787

1279 Oakmead Parkway
Sunnyvale, California 94085-4040
(408) 720-8300

Customer No. 008791